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(54)【発明の名称】　医療用体壁穴栓塞治具

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(57)【特許請求の範囲】

【請求項１】形状回復温度が20～70℃の形状記憶樹脂からなり、少なくとも一端に鍔部を設けた医療用体壁穴栓塞治具。

【請求項２】ガイドワイヤが貫通できる細穴がある請求項１記載の医療用体壁穴栓塞治具。

【請求項３】形状回復温度が20～70℃の形状記憶樹脂からなり、少なくとも一端に鍔部があり、かつガイドワイヤが貫通できる細穴がある医療用体壁穴栓塞治具であって、該細穴に嵌合してスライドするガイドワイヤ及び形状回復前の縮小形状の該治具の寸法より小さい内径を有するカテーテルを備えた医療用体壁穴栓塞治具。

【請求項４】形状回復温度が20～70℃の形状記憶樹脂からなり、少なくとも一端に鍔部がある医療用体壁穴栓塞治具であって、形状回復前の縮小形状の該治具の最大寸

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法より大きい内径を有するカテーテル及び該カテーテル内をスライドする押し出しワイヤを備えた医療用体壁穴栓塞治具。

【発明の詳細な説明】

［産業上の利用分野］

本発明は、体腔の壁に、先天的又は後天的に生じている穴を栓塞するために使用する医療用体壁穴栓塞治具に関するものである。

このような治療を要する体壁穴としては、例えば、本来閉鎖しているべき大動脈と肺動脈の間にある先天的な動脈管開存部の穴及び動脈瘤若しくは静脈瘤を生じている血管壁の穴などがある。

動脈管開存の穴は幼児の間に手術により閉鎖する必要があり、また、動静脈瘤はこれに当たる血液の圧力を弱めないと血管が破裂し、心房又は心室中隔欠損症ではこ

のまま放置しておくとチアノーゼ等があらわれ深刻な事態を招く。

［従来の技術］

従来は、例えば、動脈管開存を治療する場合は、開胸手術により心臓からの大動脈と肺動脈との間の動脈管を結紮若しくは切断する方法が一般的に用いられている。

この手術は、開胸を行うため危険な上、胸部に手術跡が永久に残るなどの深刻な欠点がある。

また、動脈瘤などの症状の場合は、動脈瘤部の前後をバイパスする方法や動脈瘤部を人工血管でおきかえる方法等があるが危険性が大きいという欠点がある。

また、心房中隔欠損の場合は欠損部にパッチ等をあてて塞ぐが開胸を伴い、危険性も大きく負担もかかるという欠点がある。

［発明が解決しようとする課題］

本発明は、動脈管、動静脈瘻、心房又は心室中隔欠損等の体腔内の患部の壁にある穴を外科的手術によらないで閉塞することを目的とするものである。

［課題を解決するための手段］

本発明者らは、課題を解決する手段として、患部に連通している体腔内に体外から栓塞用治具を挿入して、患部の穴を該治具により栓塞する方法が外科的手術を行わない点で最善と考え、この方法を達成すべく鋭意努力を行った。

しかし、体内の穴の栓塞機能に適した治具は体内に固定するため穴の壁に引っ掛かり固定しやすい寸法と形状が必須であり、そしてこのような寸法と形状にすると栓塞治具の挿入操作は困難になるという二律背反の状況を解決する必要があり、また、体腔内の栓塞すべき穴の液圧の高い側に抜け止め機能を有する鍔部が必要であるが、動脈管開存の場合のように液圧の低い方から挿入する場合に穴の径より大きい鍔部を反対側に挿入するのは体外からの遠隔操作では非常に困難であるという問題点がある。

本発明者らは、これを解決するには、挿入時には挿入に適した縮小形状で挿入し、患部を栓塞する場合には栓塞に適した別の形状に体内で変化させる方法しかなく、このため、温度により形状が変化する形状記憶物質よりなる栓塞治具を用いる方法に想到した。

また、形状記憶物質の内で、加工性がよく、体腔内への密着性の点から形状記憶樹脂が適している点に着目して、形状記憶樹脂を用いた治具により鋭意研究を行い、本発明を完成するに至った。

すなわち、本発明は、次の各項の医療用体壁穴栓塞治具からなるものである。

（１）形状回復温度が20～70℃の形状記憶樹脂からなり、少なくとも一端に鍔部を設けた医療用体壁穴栓塞治具。

（２）ガイドワイヤが貫通できる細穴がある項１記載の医療用体壁穴栓塞治具。

（３）形状回復温度が20～70℃の形状記憶樹脂からなり、少なくとも一端に鍔部があり、かつガイドワイヤが貫通できる細穴がある医療用体壁穴栓塞治具であって、該細穴に嵌合してスライドするガイドワイヤ及び形状回復前の縮小形状の該治具の寸法より小さい内径を有するカテーテルを備えた医療用体壁穴栓塞治具。

（４）形状回復温度が20～70℃の形状記憶樹脂からなり、少なくとも、一端に鍔部がある医療用体壁穴栓塞治具であって、形状回復前の縮小形状の該治具の最大寸法より大きい内径を有するカテーテル及び該カテーテル内をスライドする押し出しワイヤを備えた医療用体壁穴栓塞治具。

（５）形状回復温度が20～70℃の形状記憶樹脂からなり、両端に鍔部を設けた医療用体壁穴栓塞治具。

（６）両端の鍔部を結ぶ細径の部分の長さが縮小する形状に記憶させた形状記憶合金又は形状記憶樹脂から形成された項２又は５記載の医療用体壁穴栓塞治具。

（７）形状記憶樹脂が造影剤を含有するものである項１．２、３、４．５又は６記載の医療用体壁穴栓塞治具。

（８）粗面化表面を有する項１、２．３、４、５．６又は７記載の医療用体壁穴栓塞治具。

（９）抗血栓性材料を表面に塗布した項１、２．３、４．５、６、７又は８記載の医療用体壁穴栓塞治具。

（10）ガイドワイヤが貫通できる細穴がある項５記載の医療用体壁穴栓塞治具。

本発明に用いる形状記憶樹脂は、体温との関係で一定範囲内の形状回復温度及び体内に半永久的に設置するため、生体適合性があるものであれば、特に制限がなく、どのような形状記憶樹脂でも使用することができる。例えば、市販のポリノルボネン系、スチレン－ブタジエン共重合体系、ポリウレタン系、トランスイソプレン系などを使用することができる。

本発明に用いる形状記憶樹脂の形状回復温度は体温との関係で、20～70℃である必要があり、特に30～50℃が望ましい。

この形状回復温度が20℃未満では、挿入の途中で形状が回復しやすくなり、挿入途中で形状が回復すると危険性が高く、形状回復した治具を体外に取り出すのが困難である。

また、形状回復温度が70℃を越えると、患部に達してからの形状回復が困難になる。

本発明栓塞治具は、このような形状記憶樹脂を原料として栓塞に適した形状に成形されており、これを形状回復温度以上において、挿入に適した縮小形状に変形して、該変形を冷却固定した変形形状の該治具を挿入後に再び形状回復温度以上にして元の成形形状に復元させるものである。

本発明栓塞治具において、形状回復温度が体温より高いか低いかによって挿入操作及び体内留置後の物性が大

きく相違するので、患部の状況に応じて適宜選択して広い範囲の状況に対応することができる。

すなわち、体温より低い形状回復温度の形状記憶樹脂からなる本発明治具を使用するときは、挿入時に患部に達するまでは冷却を必要とし、患部に設置してから体温又は加熱により形状を回復させる方法により設置され、体内においてはゴム状の柔軟性のある治具として存在する。

体温より高い形状回復温度を有する形状記憶樹脂を使用した場合は、挿入のときは冷却する必要はないが患部に装着後に加熱して形状を回復させる必要があり、装着後は体温で冷却されてゴム状の柔軟性がなく強度の大きい硬質の治具として体内に留置される。

本発明治具の挿入操作はX－線による透視画面をみながら行うことが多く、このため、形状記憶樹脂に造影剤をブレンドしたものを使用するのが望ましい。これにより、本発明治具の挿入位置を把握するだけでなく、形状回復及び栓塞の状況を確認することができる。

造影剤としては、無毒でX－線を遮蔽する効果のあるものであればどのようなものでも使用することができ、例えば、硫酸バリウム、タングステン、炭酸ビスマスなどを原材料の形状記憶樹脂に適宜ブレンドすることができる。

本発明の体壁穴栓塞治具の形状は、少なくとも一端に鍔部を有するものであり、この鍔部は、患部の穴を栓塞した場合に、穴の反対側に該治具がすっぽ抜けて栓塞が破れ、治具が体腔内の他の部分に漏れたりするのを防ぐものである。

故に、該鍔部の径は栓塞すべき穴より大きいものであることが必要である。

この鍔部が本発明治具の一端にのみある場合は、本発明治具が患部から外れないためには、患部の穴の液圧の高い側に鍔部を向けて穴を栓塞するのが望ましい。

本発明の治具の両側に、穴の径より大きい２個の鍔部を設け、この鍔部で患部の穴の挟むように設置すれば、体内の液圧が瞬動的に変動しても該栓塞治具が外れない点で望ましい。

本発明治具の鍔部の形状は、患部の穴の径より大きい径を有し、患部の穴の形に適合するものであればどのような形状も使用することができる。

例えば、第１～2図の形状の鍔部を使用することができる。

第２図の円錐形状の場合は特に鍔部として区別がない形状であるが、円錐形状の最大径は患部の穴の径より大きく、円錐形状の最小径は患部の穴の径よりも小さいので、これが患部の穴に嵌合して、最大径の部分が鍔部となって患部の穴を栓塞することができる。このような形状も本発明治具の鍔部として機能する。

本発明治具として、ガイドワイヤ用の貫通細穴を設けたものを好適に使用することができる。

すなわち、該細穴付き治具を使用する場合、まず、ガイドワイヤを患部まで挿入し、ついで、該ガイドワイヤを本発明治具の細穴に通し、ついでカテーテルを該ガイドワイヤに通し、カテーテルの先で本発明治具を押せば、本発明治具はガイドワイヤに誘導されて容易に患部まで入る。

この場合、カテーテルに温度制御された生理食塩水などを通すことにより、本発明治具の形状を挿入形状に維持したり、回復形状に変化させたりすることができる。

この場合のカテーテルの内径はガイドワイヤの径より勿論大きく、挿入される縮小形状の本発明治具の寸法よりも小さい内径であることが押し込むためには必要である。

このような細穴付き治具は、患部に栓塞用として設置した場合は、細穴の部分だけ疎通しているので完全に閉鎖されないが、ガイドワイヤ用の貫通穴は細いので殆ど穴が無い場合と同様の閉鎖効果を与える。

本発明治具の態様として、かかるカテーテルとガイドワイヤを備えた医療用体壁穴栓塞治具を好適に使用することができる。

また、別の挿入方法として、まず、ガイドワイヤを同じく患部まで挿入して、これにカテーテルを通して、ガイドワイヤに導かれながら、カテーテルを患部まで挿入してから、ガイドワイヤを引き抜いて、カテーテルをそのまま体内に留置させる。

ついで本発明治具をカテーテルの内径に通る形状に縮小変形させてからカテーテルの中に入れ、これを押し込みワイヤにより押してカテーテル内を患部まで挿入する。

この場合はカテーテル内に温度制御された生理食塩水を流すことにより患部に達するまでの本発明治具の温度を正確に制御できる利点があり、形状記憶樹脂の形状回復温度が体温より低い場合に特に有効である。

この場合のカテーテルは、前例とは逆に挿入形状の治具より大きい内径である必要がある。

このような押し込みワイヤと該カテーテルを備えた本発明治具も好適に使用することができる。

本発明治具は、挿入時の縮小形状が小さいほど望ましい。そのため、内部を空洞にすることも有効である。

また、本発明治具は、所望により、切り目をいれることができる。この切れ目により、挿入形状をさらに縮小した形状にすることができる。

このような切り目としては構造及び所望の縮小形状に応じ適宜選択して種々のものを選択でき、例えば、第20図及び第21図に例示した切り目が挙げられるが、かかる切り目を入れると挿入形状をさらに寸法が縮小したもの又は径を細くしたものにすることができる。

本発明を実施例の図面により、さらに具体的に説明する。

第１図は、本発明の栓塞治具の基本的形状であり、円

筒形の中央部の両端に大小二つの鍔部1,2を有している体壁穴栓塞治具である。

この本実施例治具は、挿入時は、鍔部は内側又は外側に曲げられ患部の穴に入る径に変形しており、患部の穴に挿入してから第１図のような両端に鍔部が復元して患部の穴を両側から鍔部で固定するとともに、これが両側の体液の流通を栓塞することができる。

また、この第１図の実施例の治具の中央円筒形の中心線に沿ってガイドワイヤが嵌合して円滑にスライドする程度の径の穴を設けたものを好適に使用することができる。

この穴にガイドワイヤを通して挿入操作を容易にすることができる。

第２図は円錐形状であり．患部の穴がこの円錐形状の最高径と最小径の中間付近の径になるように設定し、患部の穴の液圧の大きい側に径の大きい方を向けて該穴に嵌合させ、患部の穴を栓塞することができる。この場合．大きい径の部分が鍔部となって穴を栓塞するとともに．該治具が反対側に抜けるのを防いでいる。この場合．円錐形状の角度は、患部穴の形状によって適宜選択されるが、先端の角度が鋭角になるほど治具が患部に固定しやすくなる。

この場合、第３図のように、内部が空洞の形状にすると．挿入時の変形形状の寸法を大きく縮小することができる点で便利である。

第４図は円錐形状の治具の頂点にも第２の鍔部を付けたものである。これにより．体液圧に脈動があっても脱落を防止することができる。

第５図は、中央部がくびれた形状のものであり．この場合は、形状が中心軸に対して対称でなく、患部の穴の形状に合わせて異方性になっており．患部に挿入してから形状回復前に回転できるようにワイヤ用の穴が２個開けてある。これに先端を二股にしたワイヤの先端を通すと．ワイヤの回転によって治具を所望の角度に回転することができる。

しかも、この穴は非貫通であるので．閉鎖効果は完全である。これは後述のカテーテル内を移動する実施例の方式で挿入することができる。

第６図は円錐形状の両端に鍔部を設けたものである。

第７図は第６図の断面の一例であるが内部が空洞になっているので．挿入時に形状をさらに小さく縮小することができる。

第８図は円錐形状鍔部が両端にあるものであり．第９図の断面構造のように大きい方の円錐鍔部を空洞にして挿入形状を縮小しやすくすることができる。

第10図は本発明栓塞治具の基本形状であり、円筒形の中央部の両端に２個の鍔部1,2を有している体壁穴栓塞治具である。該鍔部1,2は中央部で対照の構造を形成しており、各鍔部はおわんを途中まで裏返したような構造を有している。

この本実施例治具は、挿入時においては、第16図に示されるように鍔部は外側に曲げられ．患部の穴に挿入してから第10図のような元の形状に復元し、患部の穴を両側から鍔部で固定するとともに、両側の体液の流通を遮断することができる。

また、この第10図の実施例の治具の中央部付近には、ガイドワイヤが嵌合して円滑にスライドする程度の穴３を設けたものを好適に使用することができる。

この穴にガイドワイヤを通して挿入操作を容易にすることができる。

第11図は、２個の鍔部は．大きさが異なり対称形状になっておらず．これによって圧力の差による該治具の抜けを防止することができる。

第12図は、鍔部1,2を連結する部分が形状記憶樹脂又は形状記憶合金製のコイル状のものによって形成されている。挿入時にはこのコイルは長手方向に延びた状態で患部に到達すると形状回復温度以上に加熱されてコイル部分の長さが短くなり、患部を圧迫する。このコイル部は形状記憶合金製コイルの方が回復力が強い点で望ましい。なお、鍔部1,2の形状は円板状又は円錐状になっている。

第13図は、第12図の鍔部の大きさが異なり、これにより圧力の差によって穴の反対側に該治具が抜けるのを防ぐものである。

第14図は、第12図の鍔部1,2が第10図のようなおわんを途中まで裏返した形状を有するものである。

第15図は、第12図の鍔部1,2が第11図のように非対称であり、かつ各鍔部はおわんを途中まで裏返した形状を有している。

第17図及び第18図のように、切れ目を入れることにより．挿入形状をさらに縮小又は径を細くして挿入を容易にすることができる。第18図は切れ目によって鍔部がテープのように長く変形させることができる。本発明栓塞治具に用いる切れ目はこれらに限定されるものでなく、切れ目により縮小できたり．径を細くしたりするものであればどのようなものでも採用することができる。

所望により．第19図のように、体壁穴栓塞治具の表面に穴７をあけることができる。これによって、体壁穴栓塞治具はさらに容易に変形しやすくなる。その上．多数の穴７は体壁穴栓塞治具を体内に固定した後で．患部の廻りに、生体組織の形成を促進する利点がある。

第20図及び第21図のように、切り目を入れることにより．挿入形状をさらに縮小又は細い径にして挿入を容易にすることができる。第21図は、切り目によって円錐状部分をテープのように長く変形させることができる。本発明栓塞治具に用いる切り目はこれらに限定されるものでなく、切り目により形状を縮小できたり、径を細くできたりするものはどのようなものでも採用することができる。

本発明栓塞治具として．表面を粗面化したものを好適

に使用することができる。

組面としては、該治具の表面と体壁との間が滑らない効果を与えるものはどのようなものでもよく、例えば、表面に凹又は凸の多数の横溝を設けたもの、凹穴又は凸瘤を多数設けたもの、スポンジ状の材質による多孔性面及び植毛表面などを好適に使用することができる。

所望により、本発明体壁穴栓塞治具は、生体適合物質、特に、抗血栓性材料によってコーティングすることができる。

例えば、本発明体壁穴栓塞治具の表面は、テフロン、シリコン、ポリウレタン、カルデオサン（cardiothane、商標名）のようなポリマー又はヘパリン若しくはウロキナーゼなどのような抗血栓性材料を体壁穴性塞治具の表面に被覆させることができる。

第26図は、治具押し込み用兼温度制御用として機能するカテーテル及び栓塞治具導入用ガイドワイヤを備えた本発明医療用体壁穴栓塞治具の一実施例を示す。

以下に、この実施例の治具の使用方法を説明する。

例えば、動脈管開存の治療の場合、まず、ガイドワイヤ13を従来の手法の手作業により、大腿静脈から大動脈と肺動脈の間の患部の動脈管の部分まで挿入し、このガイドワイヤ13を体内に設置したままで、このガイドワイヤを治具挿入の案内導入線として、例えば、形状回復温度40℃の形状記憶樹脂によって製造した体壁穴栓塞治具を挿入しやすい形状11に変形し、これに設けた穴16にガイドワイヤ13を通し、さらに、カテーテル12をガイドワイヤ13に通し、カテーテル12の先端部17で、栓塞治具11を押しながら患部まで挿入する。

Ｘ－線透視の観察下の操作により、該治具を患部の動脈管に到達させ、患部の穴にちょうど嵌合させてから、カテーテル12に例えば45℃の生理食塩水をルーメン15から流し、嵌合した治具の一端又は両端に鍔部の形状を回復させて患部の穴に栓塞治具を固定させる。

ついで、ガイドワイヤ13を治具の穴から、カテーテル12の先端をてこにして引き抜き、形状を回復した本実施例治具を患部に留置して、カテーテル12とガイドワイヤ13を体外に抜き取って治療が完了する。

この場合、体内に留置された該治具は体温で冷却され次第に固くなり体壁穴の形状に適合して樹脂状となる。

本実施例では、これらの操作中の状況をＸ－線透視で明確に把握するために、材質の形状記憶樹脂には造影剤が添加され、カテーテルの先端には補強も兼ねて細い金属リング18が埋没されている。

さらに、別の使用方法で実施する第27図の実施例について説明する。この実施例治具の場合は、第26図の実施例と同様に、まず、ガイドワイヤ（図示していない）を患部まで挿入し、このガイドワイヤをガイドとして、カテーテル22を挿入設置してからガイドワイヤを体外に引き抜く。

挿入位置が浅い場合は、ガイドワイヤなしで最初から

カテーテル22を挿入することができる。

ついで、ストッパー部25を有する先端部26に体壁穴栓塞治具21を突き刺した押し出しワイヤ23をカテーテル22の内部をスライドして挿入する。

この場合は、本発明治具の細穴は第26図の実施例のようにガイドワイヤをスライドしないので貫通穴である必要はなく、また、穴を２個にして押し出しワイヤの先端を二股にしてこれに通しておくと、本発明治具を挿入位置でガイドワイヤの回転とともに回転させることができ、異方性のある形状の場合に特定の角度の位置まで回転させて嵌合させることができるので便利である。

この実施例の場合の形状記憶樹脂は形状回復温度が体温より低い、例えば、30℃のものを使用することができる。

この場合、カテーテル22の中に、例えば、25℃の生理食塩水を流すことにより、該治具の温度を正確に制御でき、挿入途中での形状の回復を確実に阻止することができる。

また、操作ミスにより、患部に達する前に温度が上がっても形状の拡大をカテーテルが押さえるので、容易に体外に取り出すことができる。

この押し出しワイヤにより患部の穴に治具を挿入したのち、カテーテル22の冷水を止めて形状を回復させて患部の穴を栓塞することができる。

第28図は、穴を開けていない治具の場合の実施例を示すものであり、この場合は、先端の嵌合部がなく、ストッパーの先端に凹部がありこの凹部に本発明治具を変形させて押し込んで固定している。この方法により所望の角度に回転させることもできる。

温度を上げると栓塞治具が軟化して形状回復とともに嵌合部の形状が変わりストッパーの凹部から外れるようになっている。

このようなストッパーと変形治具との接続は、押し出しワイヤの先端に設けたボール28を、第３図又は第９図のような栓塞治具の中空の鍔部で包むような形状に変形して固定し、先端ボール28と変形治具を、例えば、第29図のように接続し、形状回復が第３図又は第９図のように復元するとともに先端ボール28と治具の接続固定が分離する構造にすることもできる。

このようなワイヤと本発明治具の接続を用いれば、浅い挿入の場合は、ガイドワイヤの先端にこの方式で栓塞治具を固定してカテーテルを用いずに挿入することができる。

第28図の実施例の他の部分は第27図の実施例と同様にすることができる。

第28図の治具及び第27図において貫通していない細穴を有する治具を用いた場合は貫通細穴がないので完全に患部の穴を閉鎖する点に特徴がある。

［発明の効果］

本発明の体壁穴栓塞治具は、形状記憶樹脂を材質とし

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ている結果、単に、挿入時と栓塞時の形状変化に貢献するばかりでなく、挿入嵌合操作にもその特性を活用することができ、体腔内の患部の穴を開腹または開胸手術によらない治療を容易にできる利点が大きく、医療機器として非常に有用である。

【図面の簡単な説明】

第１図、第17図、第18図及び第19図は本発明栓塞治具の一実施例の斜視図であり、第２図、第６図、第８図、第20図及び第21図は、本発明体壁穴栓塞治具の他の実施例の形状を示す側面図であり、第10～15図は他の実施例の形状を示す側面図（ａ）と断面図（ｂ）であり、第３図、第４図、第５図、第７図、第９図、第22図及び第25図は同じく他の実施例の構造を示す縦断面図であり、第16図は第10図と第11図の縮小形状の側面図であり、第23＊

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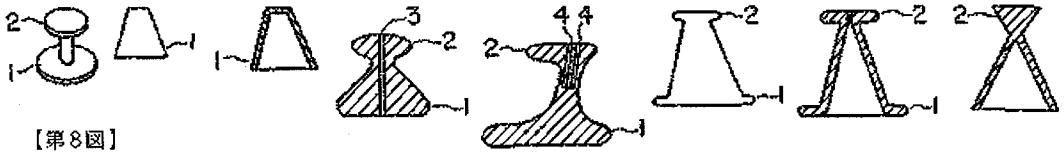
＊図は他の実施例の斜視図であり、第24図はその断面図であり、第26～28図は、カテーテル及びワイヤを備えた場合の本発明体壁穴栓塞治具の実施例の構造を示す断面図であり、第29図は押し出しワイヤと本発明治具の挿入時の接続の一例を示す断面図である。

図中の符号は、1;第１鍔部、2;第２鍔部、3;貫通穴、4;非貫通穴、5;切り目、6;凹凸溝、7;凹穴、8;植毛、11;体壁穴栓塞治具、12;カテーテル、13;ガイドワイヤ、14;ルーメン、15;温水用ルーメン、16;貫通穴、17;カテーテル先端部、18;金属リング、21;体壁穴栓塞治具、22;カテーテル、23;押し出しワイヤ、24;ルーメン、25;ストッパー、26;先端部、27;冷水用ルーメン、28;先端ボールである。

【第１図】 【第２図】 【第３図】 【第４図】 【第５図】 【第６図】 【第７図】 【第９図】



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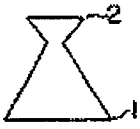
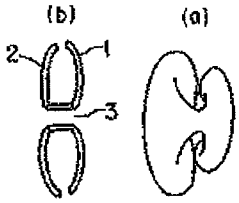


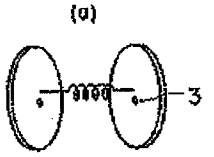
【第１０図】

【第１１図】

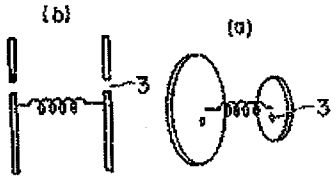


【第１２図】

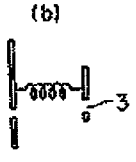
【第１３図】

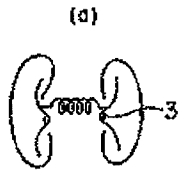


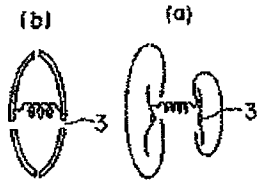
【第１４図】

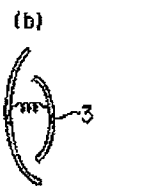


【第１５図】









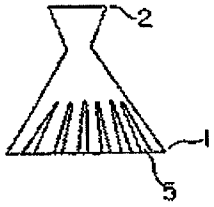
【第16図】

【第17図】

【第18図】

【第19図】

【第20図】



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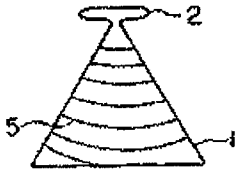

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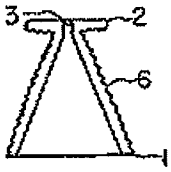

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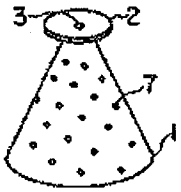

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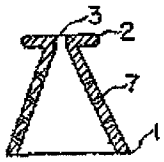

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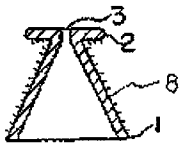
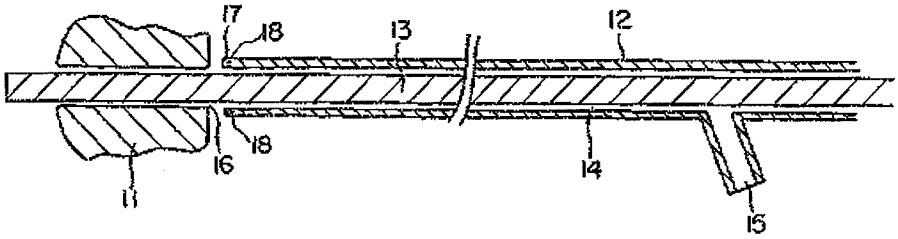


【第26図】



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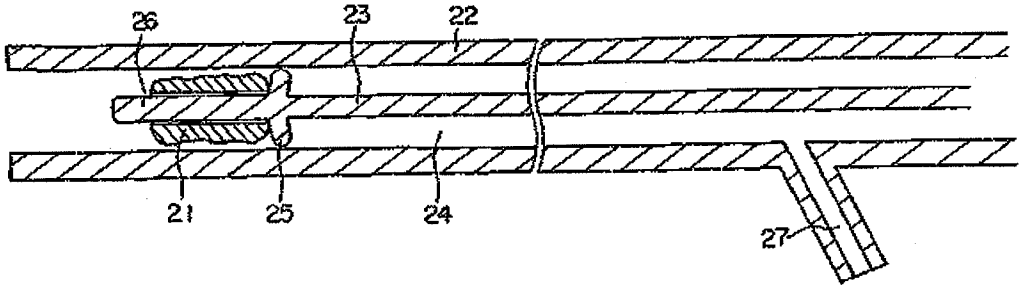
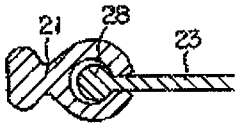


【第29図】



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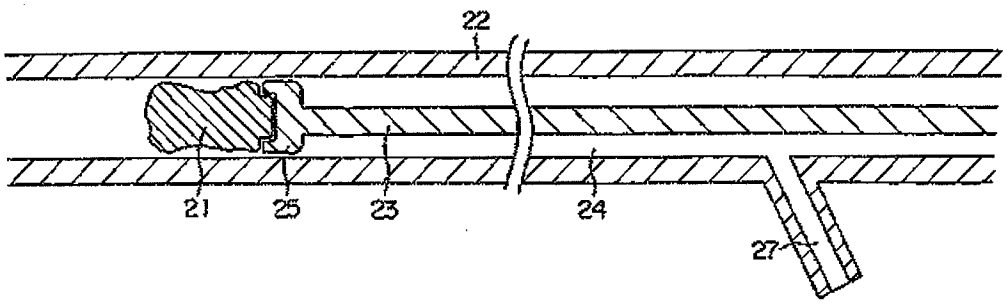

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United States Patent [19]

Kamiya et al.

[11] Patent Number: 5,192,301

[45] Date of Patent: Mar. 9, 1993

[54] **CLOSING PLUG OF A DEFECT FOR MEDICAL USE AND A CLOSING PLUG DEVICE UTILIZING IT**

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[73] Assignee: **Nippon Zeon Co., Ltd.**, Tokyo, Japan

[21] Appl. No.: **754,163**

[22] Filed: **Sep. 3, 1991**

Related U.S. Application Data

[63] Continuation of Ser. No. 460,273, July 2, 1990, ABn.

[30] **Foreign Application Priority Data**

Jan. 17, 1989 [JP] Japan 1-7916

[51] **Int. Cl.**[5] **A61B 17/04**

[52] **U.S. Cl.** **606/213**; 606/198

[58] **Field of Search** 606/198, 213, 215, 191; 128/899, 831, 843; 604/281; 600/32

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1417881	8/1988	U.S.S.R.	604/281

Primary Examiner—Michael H. Thaler

Attorney, Agent, or Firm—Frishauf, Holtz, Goodman & Woodward

[57] **ABSTRACT**

The closing plug and the closing plug device are used for closing a body defect percutaneously. During the insertion into the defect, the closing plug can be deformed to a smaller size to facilitate the insertion operation and recovered to its original larger shape after it is fitted to the defect, to thereby close the defect. The closing plug device facilitates the insertion of the closing plug into the defect. The closing plug has a flange or an enlarged portion at least at one end thereof and is made of a shape memory polymer having a shape recovery temperature in the range of 20° C. to 70° C. The closing plug device comprises a closing plug, a catheter and a guide wire or a pushing wire to aid in insertion of the closing plug to a defect.

12 Claims, 5 Drawing Sheets

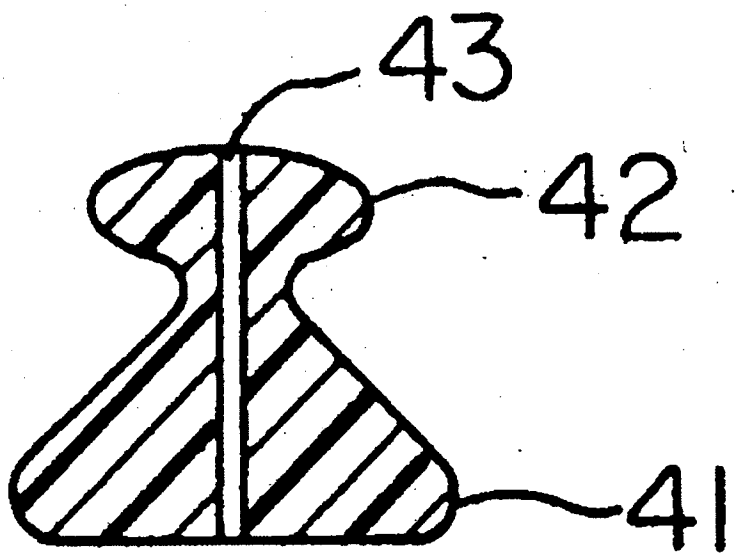


FIG. 1

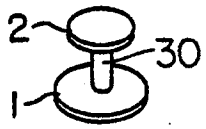


FIG. 2

FIG. 3

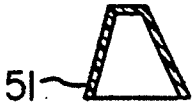


FIG. 4

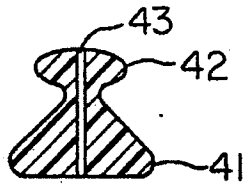


FIG. 5

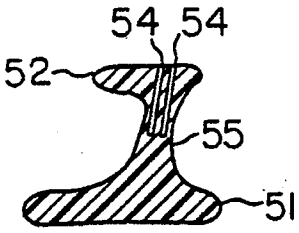


FIG. 6

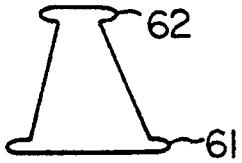


FIG. 7

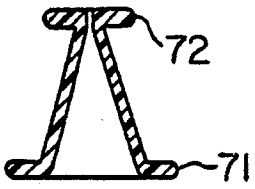


FIG. 8

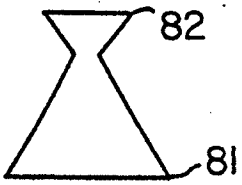


FIG. 9

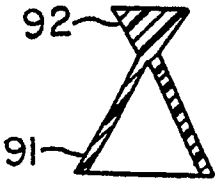


FIG. 10 (a)

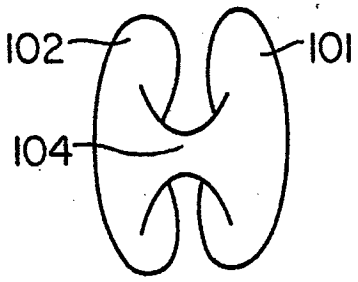


FIG. 10 (b)

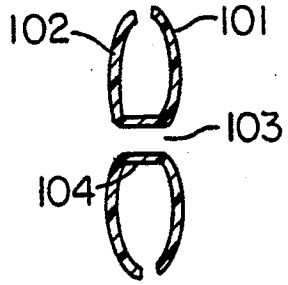
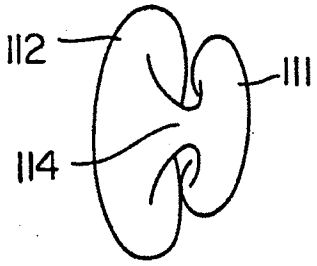


FIG. 11 (a)



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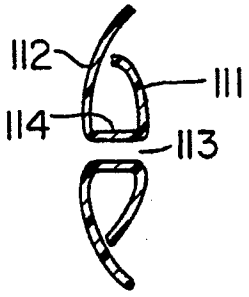
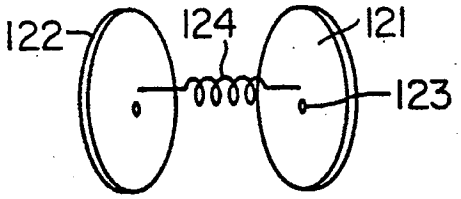


FIG. 12 (a)



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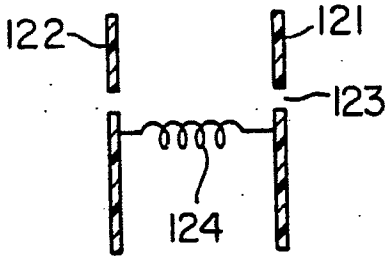
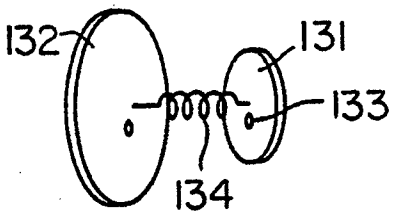


FIG. 13 (a)



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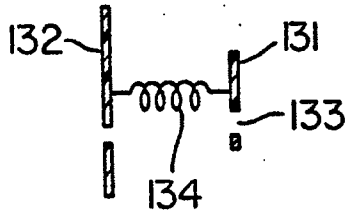
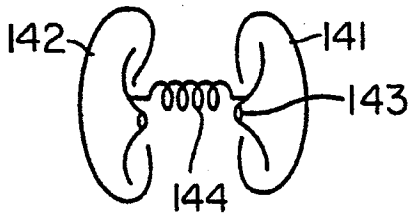


FIG. 14(a)



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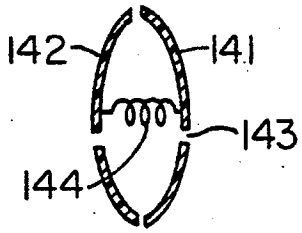
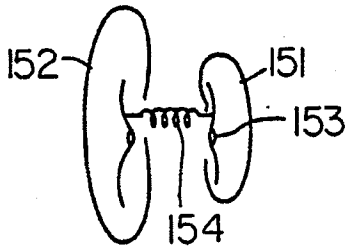


FIG. 15(a)



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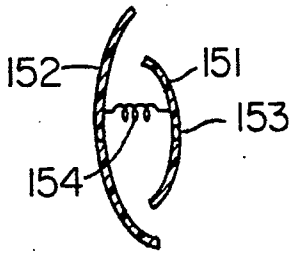


FIG. 16

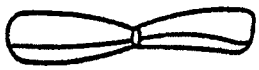


FIG. 17

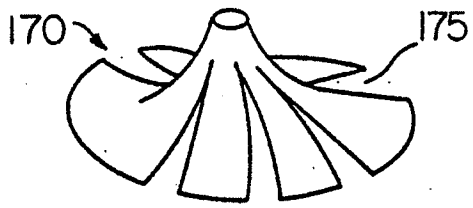


FIG. 18

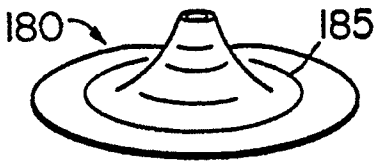


FIG. 19

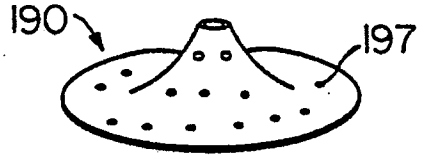


FIG. 20

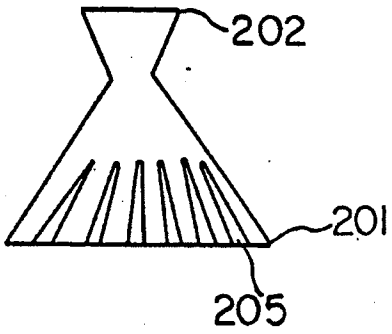


FIG. 21

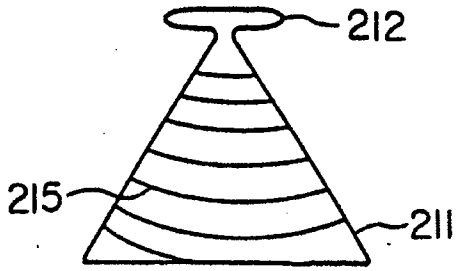


FIG. 22

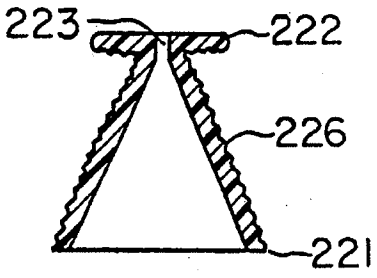


FIG. 23

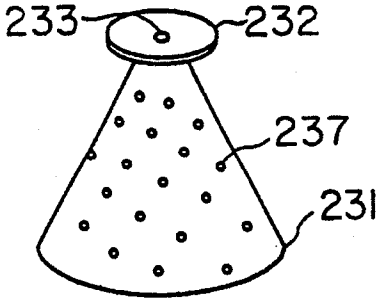


FIG. 24

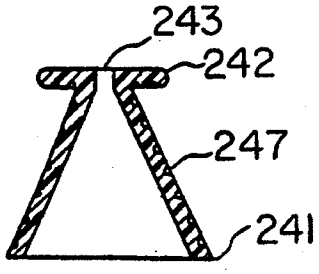


FIG. 25

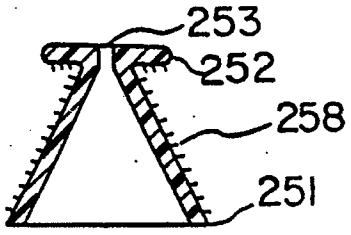


FIG. 26

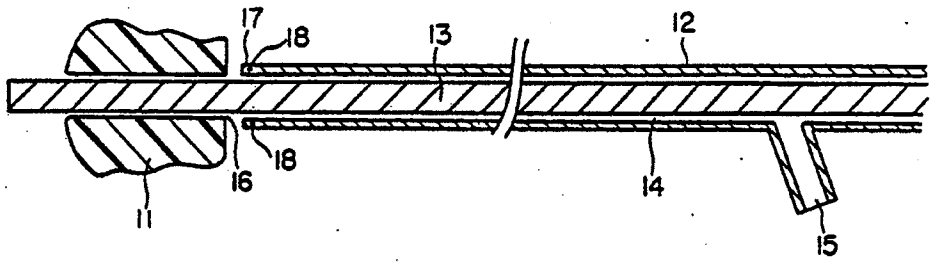


FIG. 27

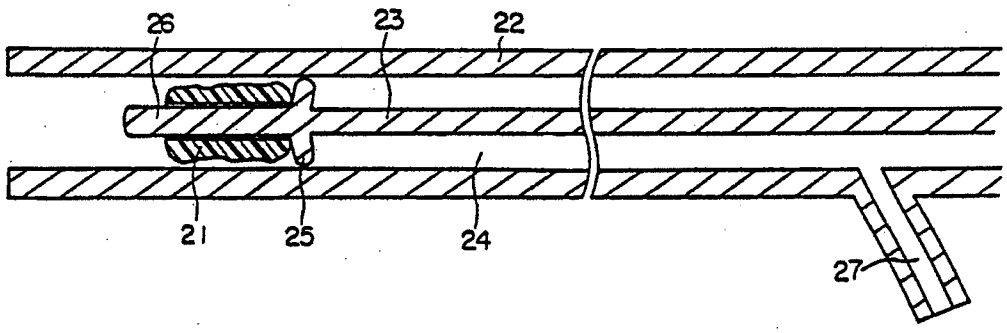


FIG. 28

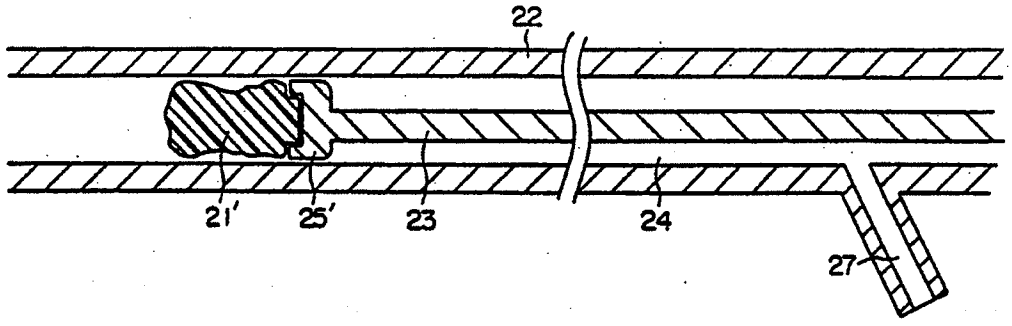
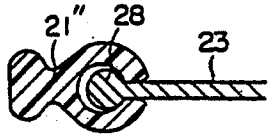


FIG. 29



CLOSING PLUG OF A DEFECT FOR MEDICAL USE AND A CLOSING PLUG DEVICE UTILIZING IT

This application is a continuation of application Ser. No. 07/460,273, filed Jan. 2, 1990, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a closing plug of a defect for medical use which is utilized to close a defect of a somatic wall of a living body, that exists either congenitally or acquiredly.

Cases of defects which require medical treatment are patent ductus arteriosus (PDA), atrial septal defect (ASD), ventricular septal defect (VSD), aneurysm, varix and so on.

In the cases of PDA, ASD and VSD, the defects must be closed by a surgical operation. And in other cases, the pressure of the blood stream must be decreased, because the high pressure of the blood stream which is caused by the existence of an aneurysm or a varix causes bursting of the defective blood vessel.

2. Prior Art

For the treatment of PDA, a thoracotomy is generally performed and the ductus arteriosus is ligated or cut. This operation has many problems. For example, it is dangerous because of the thoracotomy and the scar remains permanently.

For the treatment of an aneurysm or varix, methods of bypassing or utilizing an artificial blood vessel are generally taken. But these methods have a problem, in that the danger is not small.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a closing plug for therapeutic use within a body duct or defect.

The above described object can be achieved according to the present invention by utilizing:

1. A closing plug which has a flange at least at one end thereof and which is made of a shape memory polymer having a shape recovery temperature in the range from 20° C. to 70° C.;

2. A closing plug which has two flanges, one at each end, and which is made of a shape memory polymer having a shape recovery temperature in the range of 20° C. to 70° C.;

3. A closing plug device which comprises:

(A) a closing plug which is made of a shape memory polymer having a memory recovery temperature in the range from 20° C. to 70° C., and which has a flange at least at one end and a narrow hole through which a guide wire is passed;

(B) a guide wire which passes through the narrow hole of the closing plug so that said plug can slide over the wire; and

(C) a pushing catheter which has an inner diameter smaller than that of the closing plug which is shape in a decreased size before the recovery of the original shape; and

4. A closing plug device which comprises:

(A) a closing plug which is made of a shape memory polymer having a memory recovery temperature in the range from 20° C. to 70° C. and which has a flange at least at one end;

(B) a catheter which has an inner diameter larger than the maximum diameter of the closing plug and which is shaped in a decreased size before the recovery of the original shape; and

(C) a pushing wire which slides through the inside of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a closing plug of the invention;

FIG. **2**, FIG. **6**, FIG. **8**, FIG. **20** and FIG. **21** are respective side views of other examples of closing plugs of the invention;

FIG. **10**(*a*) through FIG. **15**(*b*) are views of still other examples of closing plugs of the invention;

FIG. **3**, FIG. **4**, FIG. **5**, FIG. **7**, FIG. **9**, FIG. **22** and FIG. **25** are vertical sectional views of still other examples of closing plugs of the invention;

FIG. **16** is an elevational view showing the decreased size of the closing plugs of FIG. **10**(*a*) and FIG. **11**(*a*);

FIGS. **17–19** are perspective views of other examples of closing plugs of the invention;

FIG. **23** is an elevational view of still another example of a closing plug, having many holes on its surface;

FIG. **24** is a cross-sectional view of the closing plug of FIG. **23**;

FIG. **26**, FIG. **27** and FIG. **28** are cross-sectional views of examples of the closing plug device of the invention, including wires and catheters; and

FIG. **29** is a cross-sectional view of a part of the closing plug device of the invention showing the connection of a pushing wire with the closing plug when the closing plug is inserted.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purpose of achieving the above-described object of the invention, the inventors considered that the best method of closing a body defect is to insert a closing plug percutaneously because it does not require surgical operations and intensive investigations were made on the method.

A closing plug is inevitably required to have a structure and a dimension which is suitable for holding and fixing at the body defect but, in general, this kind of structure and dimension makes it difficult to insert the closing plug. Thus, a solution to this contradictory situation was required. To secure the fixing of the closing plug at the defect, a flange or the like must be placed at the end of the closing plug and it must be located on the side of higher fluid pressure. However, in a case like closing a body defect at an aorta and a pulmonary artery, the closing plug is inserted from the side of lower fluid pressure and the insertion of the flange is very difficult to perform percutaneously, because the diameter of the flange is larger than that of the defect.

The inventors came to consider that the only way to solve the above contradictions is to use a plug of small size when it is inserted and which changes to a bigger size when it is fixed in a defect of the body part. For the purpose of achieving this, it was found to be useful that a plug should be made of a shape memory material.

Among various shape memory materials, shape memory polymers are suitable because of their good processability and good adhesion to the somatic wall. Thus, an intensive investigation on the utilization of shape memory polymers led to completion of the present invention.

The kind of shape memory polymer is not particularly limited in the present invention. An example of such polymer is polynorborniene, styrene-butadiene copolymer, polyurethane, transpolyisoprene and the like.

It is essential that the shape recovery temperature of the shape memory polymer utilized in the present invention is in the range from 20° C. to 70° C., preferably in the range from 30° C. to 50° C., because of the relation to the body temperature. When the shape recovery temperature is lower than 20° C., shape recovery is easier to take place during the operation of insertion. And when the shape recovery temperature is higher than 70° C., recovery of the shape at the site of closing a defect is difficult.

In the closing plug, a shape memory polymer is molded to a shape suitable for closing a defect in a body part. The molded closing plug is then deformed to a decreased size suitable to insert easily into the body part above the shape recovery temperature of the polymer and is then cooled to fix the plug to the deformed decreased-size shape. Thus, the deformed closing plug is inserted to the desired location in the body and is then warmed to above the shape recovery temperature to recover the original shape suitable for closing the body defect.

In the closing plug, the operation of the insertion plug and its physical properties are greatly dependent on whether the shape recovery temperature is higher or lower than the body temperature. So, a wide range of requirements which vary by the condition of the defect can be satisfied by choosing a suitable shape recovery temperature of the polymer.

When the shape recovery temperature is lower than the body temperature, it is necessary to cool the closing plug during the insertion in the defective body part and, after fixing the closing plug at the desired location, the original shape of the closing plug is recovered by warming or by the body temperature per se. The closing plug stays in the body as a rubbery and flexible member.

When the shape recovery temperature is higher than the body temperature, cooling during insertion is not required, but is necessary to warm it after the insertion at the desired location to cause it to recover the original shape. After the closing plug is fixed, it is cooled by the body temperature, loses its rubbery flexibility and is fixed to the body as a hard member having a high strength.

If desired, the closing plug can contain a radiopaque material to make it visible to a fluoroscope or other conventional radiographic instrument.

Any kind of a radiopaque material can be utilized so long as it is harmless and has an effect of shielding X-rays. Suitable materials are barius sulfate, tungsten, bismus subcarbonate and the like.

The closing plug comprises a flange at least at one end. The flange prevents the closing plug from slipping through the body defect into the other side of the defect and prevents fluid from flowing through the defect again. For this reason, it is necessary that the size of the flange is larger than that of the body defect.

When the closing plug has a flange only at one end, it is desirable that the flange is fixed at the side of the defect having higher fluid pressure, so that the closing plug does not fall off from the defect.

If desired, the closing plug has two flanges having a diameter larger than that of the defect and holding the defect between the two flanges. In this case, the closing plug does not fall off from the defect even if the fluid pressure in the body changes.

The flange can have any kind of shape so long as the size is larger than that of the body defect to be closed and the flange fits well to the defect. Examples of the shape of the flange are shown in FIG. 1 through FIG. 25.

A closing plug having a cone shape as shown in FIG. 2 does not have clearly defined Separate flanges. However, the maximum diameter of the cone is larger and the minimum diameter of the cone is smaller than that of the defect to be closed. This closing plug can fit into the defect, and the portion of the maximum diameter acts just in the same way as a flange part and the closing plug can effectively close the defect. Thus, a cone shape is effectively utilized as the closing plug.

If desired, the closing plug has a narrow hole through which a guide wire is passed. When the closing plug has a narrow through-hole, at first, the guide wire is inserted to the location of the defect, the proximal portion of the guide wire is passed through the narrow hole of the closing plug, then a catheter is inserted over the guide wire and the closing plug is pushed into the body by the tip of the catheter along the guide wire. Thus, the closing plug is easily carried to the location of the defect by utilizing the guide wire.

In this application, the shape of the closing plug can be either maintained in the deformed shape or it can be recovered to the original shape by passing a liquid (for example, a physiological saline) at a controlled temperature through the catheter.

The inner diameter of the catheter is naturally larger than the diameter of the guide wire and smaller than the size of the deformed closing plug so that the tip of the catheter can push the closing plug to the location of the defect.

The closing plug having a narrow through-hole cannot close the defect completely because the through-hole remains open. However, the through-hole is so narrow that the closing plug is actually as effective as that without a hole.

The closing plug device comprising the closing plug, the guide wire and the catheter is favorably utilized to achieve the object of the invention.

In another example of the insertion of the closing plug, at first, a guide wire is inserted to the location of the defect, than a catheter is inserted to the location of the defect by utilizing the guide wire, the guide wire is then pulled out and the catheter is left in the body.

The closing plug is shaped to a decreased size to pass through the inside of the catheter, placed into the catheter and transferred to the location of the defect by a pushing wire through the inside of the catheter.

This method has an advantage of controlling the temperature of the closing plug until it reaches the defect by passing a physiological saline through the inside of the catheter and is especially effective when the shape recovery temperature is lower than the body temperature. The inner diameter of the catheter must be larger than the size of the closing plug.

The closing plug device comprising the closing plug, the guide wire and the catheter is favorably utilized to achieve the object of the invention.

The smaller size of the closing plug is more desirable during the insertion. A hollow structure is effectively utilized.

It is desired that the closing plug can have a cut, so that the size of the closing plug can be further de-

creased. Various kinds of cuts can be utilized. Examples of slits are shown in FIG. 20 and FIG. 21. Smaller dimensions or smaller diameters can be achieved by such cuts.

FIG. 1 shown the basic shape of the closing plug, which as two flanges, 1, 2 of different size, being fixed at both ends of a cylindrical member 30.

The flanges 1, 2 of FIG. 1 are folded inward or outward so that they have a decreased size. After the closing plug is inserted into the defect (i.e., an opening in a body part, the opening having a rim or peripheral edge defining a boundary of the opening), the flanges restore to their original shape as shown in FIG. 1, fix the closing plug to the defect and hold it from both sides of the wall of the body part and, at the same time, the passage of the fluid through the defect stops.

Another shape of the closing plug has a narrow hole along the axis of the cylinder 30, and the size of the hole is wide enough to have a guide wire passed through and slided smoothly. A guide wire can be passed through the hole and the insertion can be facilitated.

FIG. 2 shows a closing plug 40 having a cone shape. The size of the cone is designed so that the size of the defect is smaller than the maximum diameter portion of the cone and larger than the minimum diameter portion of the cone. The larger side of the cone is placed on the side of the defect having a higher fluid pressure, because it works just like a flange, closes the defect and prevents the closing plug from falling off from the defect. The angle at the apex of the cone can be suitably selected depending on the shape of the defect. In general, a sharper angle makes fixing to the defect easier.

When the cone of FIG. 2 is modified to have a hollow structure 5; as shown in FIG. 3, the size of the closing plug 51 during the insertion can easily be decreased to a greater extent and the closing plug is used more advantageously.

FIG. 4 shows a closing plug having a flange part 41 and an additional flange part 42 at the apex of the cone. The second flange part 42 at the apex of the cone prevents the closing plug from falling off from the defect during pulse variation. The closing plug of FIG. 4 also has an elongated hole 43 therethrough which may be passed over a guide wire as explained above.

FIG. 5 shows a closing plug having a constriction 55 in the middle portion thereof, an asymmetrical shape to fit well to the shape of the defect and two holes 54 for wires along the axis so that the closing plug can be rotated in the defect before the recovery of the original shape. When a wire has two branches at the front and the branches are inserted into the two holes 54 of the closing plug, the closing plug can be rotated to a desired angle by rotating the wire.

Additionally, the holes 54 are not perforated through the closing plug, so the closing plug closes the defect completely. A closing plug of this shape can be inserted by transferring same through the inside of the catheter. This method will be shown in a later-described example in more detail.

FIG. 6 shows a closing plug having two flanges 61, 62 at the two ends of a cone 63.

FIG. 8 shows a closing plug having two cones at the two ends 81, 82. This type of the closing plug can be modified to have a hollow structure inside of the larger cone 91, and a smaller solid cone 92, as shown in FIG. 9 so that the size can be decreased more easily.

FIGS. 10(*a*) and 10(*b*) show another basic shape of the closing plug. The closing plug comprises two flanges 101, 102 of the same size, connected at two ends of a cylinder portion 104. The two flanges are arranged symmetrically with respect to the middle point of the cylinder 104 and each flange has a shape of a cup which is turned inside out.

A closing plug having this structure can be inserted while the flanges are folded as shown in FIG. 16. The flanges are recovered to the original shape of FIG. 10(*a*) when the closing plug is properly fixed to the defect. The flanges 101, 102 hold the defect from both sides and the passage of the body fluid is securely prevented.

If desired, a closing plug of FIGS. 10(*a*) and 10(*b*) is modified to have a narrow hole 103 along the axis of the cylinder 104 which is wide enough to have a guide wire passed through smoothly. A guide wire can be passed through the narrow hole to facilitate the operation of the insertion.

FIGS. 11(*a*) and 11(*b*) show a closing plug similar to the structure shown in FIGS. 10(*a*) and 10(*b*) except that the structure is not symmetrical and the two flanges 111, 112 on opposite sides of cylinder portion 114 have different sizes. This type of closing plug can be effectively utilized to prevent the closing plug from falling off from the defect by a different pressure between two sides of the wall. A narrow hole 113 can be provided to receive a guide wire.

FIGS. 12(*a*) and 12(*b*) show a closing plug comprising two flanges 121, 122 connected to opposite ends of a coil 124 made of a shape memory polymer or a shape memory alloy. Guide wire holes 123 may be provided in flanges 121, 122. The coil is shaped into an elongated form to suit the insertion to the location of the defect. When it is placed into the defect, the coil 124 is warmed to recover to its original shorter length and hold the closing plug tightly from both sides of the wall of the body part. A shape memory alloy is preferable because of the stronger recovery force. The flanges 121, 122 have a disk shape.

FIGS. 13(*a*) and 13(*b*) show a closing plug similar to the closing plug of FIG. 12(*a*) except that the flanges 131, 132, connected between coil 134, are of different sizes so that falling off of the closing plug caused by different fluid pressure between two sides of the wall can be prevented. A guide wire hole 133 may be provided.

FIGS. 14(*a*) and 14(*b*) show a closing plug similar to the closing plug of FIG. 12(*a*) except that the flanges 141, 142, connected between shape memory coil 144 have a shape similar to those shown in FIG. 10(*a*). A guide wire hole 143 may be provided.

FIGS. 15(*a*) and 15(*b*) show a closing plug similar to the closing plug of FIG. 14 except that the flanges 151, 152, connected between shape memory coil 154 are of different sizes. A guide wire hole 153 may be provided.

If desired, a closing plug member has cuts on its surface as shown in FIG. 17 and 18 (cuts 175 on member 170 in FIG. 17; cuts 185 on member 180 in FIG. 18), in order to facilitate the insertion. A flange 180 of FIG. 18 can be deformed to a long tape-like shape by the effect of cuts 185.

If desired, a closing plug 190 has many through-holes 197 opened on its surface as shown in FIG. 19. As a result, the closing plug 190 can be deformed more easily. In addition, many through-holes 197 allow formation of tissue around the defect after the closing plug is fixed.

FIG. 20 and FIG. 21 show other examples of closing plugs having cuts (205—FIG. 20; 215—FIG. 21) on its

surface to make a decreased size or diameter more easily. In the closing plug of FIG. 21, the flange 201 can be deformed tape-like by the effect of the cuts.

The cuts are not limited to those shown in the examples but any kind of cut can be utilized so as to be effective for decreasing the size or diameter of the closing plug.

As shown in FIGS. 22 to 25, a closing plug having a rough surface can be favorably utilized for the object of the invention. Any kind of rough surface can be utilized so long as the roughness is effective in fixation. Examples of rough surface structures are a surface having numbers of grooves or continuous protrusions 226 perpendicular to the direction of the axis shown in FIG. 22, a surface having numbers of indentations or isolated protrusions 237 as shown in FIG. 23, a surface having a porous structure like a sponge 247 shown in FIG. 24, a surface having numbers of hairs 258 implanted on the surface thereof as shown in FIG. 25 and the like. Guide wire holes 223, 233, 243, 253 can be provided in the embodiments of FIGS. 22-25, respectively.

If desired, the closing plug can be coated with a biocompatible material, particularly an antithrombogenic material. Such a closing plug may be coated with TEFLON, silicone, polyurethane, or an antithrombogenic polymer such as "cardiothane". Otherwise, antithrombogenic materials such as heparin or urokinase may be combined on the surface of the closing plug.

FIG. 26 shows an example of the closing plug device which comprises a closing plug, a pushing catheter and a guide wire for the insertion of the closing plug. The method utilizing the closing plug device is explained in detail in the following.

In the case of the treatment of patent ductus arteriosus, at first, a guide wire is inserted from a femoral vein to the defect between the aorta and pulmonary artery. The guide wire 13 is left at the place. A closing plug prepared from a shape memory polymer having, for example, a shape recovery temperature of 40° C. is deformed to the smaller size 11, the guide wire 13 is pierced through a narrow hole 16 of the closing plug, a catheter 12 is inserted over the guide wire 13 and then, the closing plug 11 is inserted by being pushed by the tip 17 of the catheter 12 until the closing plug reaches the area of the defect.

While the operation can be observed with a fluoroscope, the closing plug is inserted to the defect. Then, fitted to the defect to be closed, physiological saline at a temperature of 45° C. is injected to the catheter 12 through the inlet 15, and the flange is recovered to the original shape and thus the closing plug is tightly fixed to the defect to close it.

The guide wire 13 is removed from the narrow hole by using the catheter 12 the catheter 12 and the guide wire 13 are removed from the body, and the closing plug which has the recovered original shape is left at the defect in the body and thus the treatment is completed.

The closing plug is cooled by the body temperature and becomes gradually a hard material which fits well to the defect.

In the example explained here, a radiopaque material is blended with the shape memory polymer and a thin metallic ring 18 is positioned within the tip of the catheter for the purpose of observing clearly with a fluoroscope. The ring 18 is also useful for the purpose of reinforcement of the tip.

Another example of the closing plug device as shown in FIG. 27 is explained in the following. In this example, at first, a guide wire which is not show in the figure, if necessary is inserted to the defect and a catheter 22 is inserted to the defect along the guide wire in the same way as the previous example shown in FIG. 26. The guide wire is then removed from the body, leaving the catheter in the blood vessel.

Next, the tip of a pushing wire 23 is pierced through a narrow hole of the closing plug and the pushing wire 23 is inserted in the catheter.

In the case of this example, the narrow hole is not required because the closing plug does not slide over the wire as in the case of FIG. 26. It is also convenient when the closing plug has two half-way holes and the pushing wire has two branches at the tip fitted into these two holes. This is because the closing plug can be rotated by rotating the guide wire and the closing plug can be fitted well to the defect.

A shape memory polymer having a shape recovery temperature lower than the body temperature, for example 30° C., can be utilized in this example. The temperature of the closing plug can be accurately controlled by passing physiological saline at a temperature of, for example, 25° C. through the catheter 22 and thus the unfavorable recovery of the original shape during the insertion is securely prevented.

Even when the temperature of the closing plug is increased before the closing plug reaches the defect and the shape of the closing plug begins to expand, the catheter can prevent the closing plug from expanding and the removal of the closing plug is not so difficult.

After the closing plug is fitted to the defect, the shape of the closing plug can be recovered to the original shape by stopping the injection of cold water through the catheter and the hole is closed.

FIG. 28 shows an example of a closing plug device 21' which has no hole. In this example, the tip 25' of the pushing wire 23 comprises a cavity and the closing plug of the invention is deformed to fit in the cavity and be fixed to the cavity by being pushed into it. The closing plug can be rotated to a desired angle by this method.

When the temperature of the closing plug is increased, the closing plug becomes softer and can be removed from the tip of the pushing wire while the closing plug recovers the original shape thereof.

Another example of the connection between the closing plug and the tip of the pushing wire is shown in FIG. 29. A flange having a hollow structure as shown in FIG. 3 or FIG. 9 is deformed so that the flange can wrap around a ball shaped member 28 at the tip of the pushing wire 23. The ball member 28 and the deformed closing plug 21" are connected as shown in FIG. 29. When the closing plug is allowed to recover the original shape of FIG. 3 or FIG. 9, the closing plug 21" is disconnected from the ball member 28 at the tip of the pushing wire 23.

When the location of the defect is not far from the inserted position, the closing plug can be inserted and fixed by the tip of the guide wire as described in FIG. 28 and FIG. 29 without using a catheter.

Other structures shown in FIG. 28 are similar to those shown in FIG. 27.

The closing plugs utilized in FIG. 28 or FIG. 27 do not need any passing through-hole, so they can completely close the defect.

In summary, the closing plug of the present invention is made of a shape memory polymer. As a result, the closing plug can be deformed during the insertion and can recover to its original shape when fixed in place.

Also, the closing plug device allows the operation to be carried out percutaneously. Thus, it is useful in medical applications.

We claim:

1. A closing plug for closing an opening in a body part of a living body, said opening in said body part including one of a patent ductus arteriosus (PDA), atrial septal defect (ASD), ventricular septal defect (VSD), aneurysm and varix, said opening having a rim defining a boundary of said opening, and said body part having an interior surface and an exterior surface adjacent said rim of said opening, the closing plug comprising:

a body portion having opposite end portions; and

an enlarged portion at each opposite end portion of said body portion, said enlarged portions each having a predefined size and shape which is larger than said opening to be closed and larger than a cross sectional size of said opening to be closed; and

wherein at least said enlarged portions are made of a shape memory polymer having a shape recovery temperature in the range of from 20° C. to 70° C., such that at least said enlarged portions are physically able to be reduced in size to a size to freely pass through said opening without further enlarging said opening, prior to introduction into said opening in the body part, and are able to be enlarged to their respective original predefined larger size and shape after insertion through said opening in said body part and after exposure to a temperature within said shape recovery temperature range so that said enlarged portions contact said interior surface and exterior surface, respectively, of said body part adjacent said rim of said opening to close said opening and to prevent said closing plug from coming out of said closed opening;

said closing plug having a narrow through-hole therein, which extends between each of said enlarged portions and which provides effective closure of said opening of said body part, and through which a guide wire is passable between each of said enlarged portions.

2. A closing plug as claimed in claim 1, wherein:

said enlarged portions comprise respective flanges;

said body portion comprises a narrower portion between said flanges;

said narrower portion of the closing plug between said flanges is made of one of a shape memory alloy and a shape memory polymer, such that the length of said narrower portion is able to become shorter when the shape of said narrower portion is recovered after being subjected to the shape recovery temperature.

3. A closing plug as claimed in claim 1, wherein the shape memory polymer contains a radiopaque material.

4. A closing plug as claimed in claim 1, wherein said closing plug has a rough outer surface.

5. A closing plug for closing an opening in a body part of a living body as claimed in claim 4, wherein the enlarged portions have a number of cuts therein.

6. A closing plug as claimed in claim 1, wherein the outer surface of said closing plug is coated with an antithrombogenic material.

7. A closing plug for closing an opening in a body part of a living body as claimed in claim 1, wherein the enlarged portions have a number of cuts therein.

8. A closing plug device which comprises:

(A) a closing plug for closing an opening in a body part of a living body, said opening in said body part including one of a patent ductus arteriosus (PDA), atrial septal defect (ASD), ventricular septal defect (VSD), aneurysm and varix, said opening having a rim defining a boundary of said opening, and said body part having an interior surface and an exterior surface adjacent said rim of said opening, the closing plug comprising:

a body portion having opposite end portions; and

an enlarged portion at each opposite end portion of said body portion, said enlarged portions each having a predefined size and shape which is larger than said opening to be closed and larger than a cross sectional size of said opening to be closed; and

wherein at least said enlarged portions are made of a shape memory polymer having a shape recovery temperature in the range of from 20° C. to 70° C., such that at least said enlarged portions are physically able to be reduced in size to a size to freely pass through said opening without further enlarging said opening, prior to introduction into said opening in the body part, and are able to be enlarged to their respective original predefined larger size and shape after insertion through said opening in said body part and after exposure to a temperature within said shape recovery temperature range so as to contact said interior surface and said exterior surface, respectively, of said body part adjacent said rim of said opening to close said opening and to prevent said closing plug from coming out of said closed opening;

said closing plug having a narrow through-hole therein, which extends between each of said enlarged portions and which provides effective closure of said opening of said body part, and through which a guide wire is passable between each of said enlarged portions;

(B) a guide wire which passes through said narrow through-hole of said closing plug so that said closing plug is slidable over the guide wire; and

(C) a pushing catheter having an inner diameter smaller than the outer dimension of said closing plug when said enlarged portions are at their respective reduced size before they are enlarged to their respective original predefined larger size and shape.

9. A closing plug device as claimed in claim 8, wherein said shape memory polymer contains a radiopaque material.

10. A closing plug device which comprises:

(A) a closing plug for closing an opening in a body part of a living body, said opening in said body part including one of a patent ductus arteriosus (PDA), atrial septal defect (ASD), ventricular septal defect (VSD), aneurysm and varix, said opening having a rim defining a boundary of said opening, and said body part having an interior surface and an exterior surface adjacent said rim of said opening, the closing plug comprising:

a body portion having opposite end portions; and

an enlarged portion at each opposite end portion of said body portion, said enlarged portions each having a predefined size and shape which is larger than said opening to be closed and larger than a cross sectional size of said opening to be closed; and

wherein at least said enlarged portions are made of a shape memory polymer having a shape recovery temperature in the range of from 20° C. to 70° C., such that at least said enlarged portions are physically able to be reduced in size to a size to freely pass through said opening without further enlarging said opening, prior to introduction into said opening in the body part, and are able to be enlarged to their respective original predefined larger size and shape after insertion through said opening in said body part and after exposure to a temperature within said shape recovery temperature range so as to contact said interior surface and said exterior surface, respectively, of said body part adjacent said rim of said opening to close said opening and to prevent said closing plug from coming out of said closed opening;

said closing plug having a narrow through-hole therein, which extends between each of said enlarged portions and which provides effective closure of said opening of said body part, and through which a guide wire is passable between each of said enlarged portions;

(B) a catheter having an inner diameter larger than the maximum outer dimension of said closing plug when said enlarged portions are at their respective reduced size, and having said reduced size closing plug slidably received therein; and

(C) a pushing wire which is slidable through the inside of the catheter for pushing said closing plug through the interior of said catheter and through the opening in said body part which is to be closed by said closing plug.

11. A closing plug device as claimed in claim **8** or **10**, wherein said closing plug has a rough outer surface.

12. A closing plug device as claimed in claim **8** or **10**, wherein the outer surface of said closing plug is coated with an antithrombogenic material.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,192,301
DATED : March 9, 1993
INVENTOR(S) : KAMIYA et al

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page,

Section [56] References Cited,

Under "U.S. Patent Documents",

Change "4,936,204" to --4,836,204--.

Signed and Sealed this

Seventh Day of June, 1994

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks